EXHIBIT M

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

ALLERGAN USA, INC., and ALLERGAN INDUSTRIE, SAS,

Plaintiffs,

v.

MEDICIS AESTHETICS, INC., MEDICIS PHARMACEUTICAL CORP., VALEANT PHARMACEUTICALS NORTH AMERICA LLC, VALEANT PHARMACEUTICALS INTERNATIONAL, VALEANT PHARMACEUTICALS INTERNATIONAL, INC., and GALDERMA LABORATORIES, L.P.

Defendants.

Case No. 8:13-cv-01436 AG (JPRx)

REPORT OF GLENN D. PRESTWICH, Ph.D.

FEBRUARY 17, 2015

CONFIDENTIAL MATERIAL SUBJECT TO PROTECTIVE ORDER

180. For these reasons, the asserted claims of the '475 Patent are obvious in light of the disclosures in *Hunter*, *Sadozai*, and *Reinmuller II*.

181. Element-by-element charts for these can be found at Exhibit D..

2. Previously Known Pre-mixing of Lidocaine and Restylane/Perlane/Juvederm Product

182. Additionally, as noted above in paragraph 145, I have been told that practitioners were mixing lidocaine and HA-BDDE dermal fillers using connectors before injection of the dermal filler from the period shortly after the HA-BDDE fillers were approved and available on the market.

183. As noted above in Paragraphs 169 and 170, Allergan asserts that Restylane-L and Perlane-L practice all elements of the asserted claims of the '475 Patent, while their asserted Juvederm XC products practice select claims of the '475 Patent. As I note in paragraph 169, the only difference between these products and the same brand names without lidocaine is the lidocaine.

184. Once the lidocaine had been added, I have been told that practitioners would inject the sterile substance into their patients as they would with any dermal filler. I have been told that the product remained sterile and clinically useful before injection took place.

185. The successful practice of adding lidocaine to HA dermal fillers would make it obvious to a POSITA that adding lidocaine during the manufacturing process was able to be done and could result in a final, lidocaine-containing dermal filler that had the elements of the asserted claims in view of the common knowledge in the art about HA fillers and lidocaine such as that described in this report. Variations on degree of crosslinking, concentration of lidocaine, and amount of free HA had all been disclosed in the prior art and would all be obtainable through experimentation.

186. For the foregoing reasons, the asserted claims of the '475 Patent would have been obvious in light of the pre-mixing of lidocaine with crosslinked HA dermal fillers of the Restylane and Juvederm families performed by practitioners in view of the common knowledge.

3. Debacker

187. *Debacker* discloses and describes compositions comprised of an insoluble hydrogel of a crosslinked polymer contained within an aqueous solution of the polymer.[179] More specifically, *Debacker* concerns a dermal filler of HA-BDDE in uncrosslinked HA at a 2-to-1 ratio.[180] *Debacker* also teaches the packaging and autoclave sterilization of this filler.[181]

188. Element-by-element charts for *Debacker* can be found in Exhibit D.

a. In combination with *Sadozai*

189. *Sadozai* teaches an HA-BCDI composition for use in tissue augmentation.[182] More than this teaching, however, *Sadozai* also teaches that lidocaine can have a "synergistic effect" on the rheological properties of crosslinked HA and provide stabilization during and following autoclave sterilization.[183]

190. For the general reasons discussed above in Section VIII.A, a POSITA would have been highly motivated to modify the explicitly disclosed filler in *Debacker* to include lidocaine. This is particularly true in view of *Sadozai*, given the pain relief possibilities and potential synergies created by adding lidocaine to such a composition.

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[179] *Debacker*, 3:15-19.

[180] *Id.*, Example 2.

[181] *Id.*, 14:22-24.

[182] *Sadozai*, Abstract.

[183] *Id.*, Example 21; Fig. 7; paras. [0068] and [0069].